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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/814,858	03/31/2004	Rakesh Tuli	U 015125-9	5596
140	7590	04/04/2006	EXAMINER	
LADAS & PARRY 26 WEST 61ST STREET NEW YORK, NY 10023			MARVICH, MARIA	
			ART UNIT	PAPER NUMBER
			1633	

DATE MAILED: 04/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/814,858

Applicant(s)

TULI ET AL.

Examiner

Maria B. Marvich, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 January 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 3-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***DETAILED ACTION***

Claims 1, and 3-10 are pending in the application.

***Claim Rejections - 35 USC § 112***

The rejection of claims 1-10 under 35 U.S.C. 112, second paragraph, is withdrawn in response to Applicant's amendment to the claims.

Claims 1, and 3-10 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record. Applicant's arguments filed 1-19-2006 have been fully considered, but are not persuasive. Applicants traverse the instant rejection on the grounds that support for the phrase "up to 70% homologous" is found in the specification as filed, wherein it explains that sequence variations to the extent of 30% may not affect the function of the TAM and TIM. Applicant also make reference to various US patents which make mention of homologous sequences in the claims. Contrary, to Applicant's assertions, the rejection for lack of written description was not based upon lack of antecedent basis in the specification as filed of the instantly claimed invention. On the contrary, the rejection was based upon the observation that at the time of filing of the instant invention, Applicant's were not in possession of the full scope of the claimed invention. As stated in the prior Office Action, an adequate written description of the invention defined by the

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claims requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is the knowledge in the prior art and/or a description as to the availability of a representative number of species of claimed nucleic acid sequences. Applicants claim a large genus of sequences that are up to 70 % homologous with TAM and/or TIM. However, applicants have not provided structural information that would demonstrate what the structural requirements of TAM and TIM are such that a bidirectional promoter can be identified from the large genus of sequences. Moreover, it was previously stated that, in the instant case, applicants have defined two sequences that in conjunction generate a bidirectional promoter. However, applicants have not demonstrated that variance of any up to 30% of the nucleotides would result in a promoter that can function similarly. Therefore, the relationship between structure and function is unclear as neither applicant nor the prior art provide a correlation between the structures of TAM and TIM and the ability to promoter bidirectional expression. Given the large size and diverse nature of the recited sequences and the inability to determine which will also possess the ability to mediate bidirectional expression, it is concluded that the invention must be empirically determined. In an unpredictable art, the disclosure of TAM and TIM would not represent to the skilled artisan a representative number of species sufficient to show applicants were in possession of claimed genus. Applicants have not properly addressed the merits of these grounds of rejection set forth in the prior Office Action. Moreover, Applicant's reference to other issued US Patents that include reference to homologous

sequences, is not applicable in the instant case, since the specifications of those issued US Patents are not coextensive in scope with the claimed invention.

#### Claim Rejections - 35 USC § 102

Claims 1, and 3-10 remain rejected under 35 U.S.C. 102(b) as being anticipated by Sawant et al (Theor Appli Genet, 2001, Vol 102, pages 635-644 as evidenced by pUC19; see entire document), for the reasons of record. Applicant's arguments filed 1-19-2006 have been fully considered, but are not persuasive. Applicants traverse the instant rejection on the grounds that the Sawant et al. reference teaches unidirectional function of the TAM + TIM, however the claims in this application define a bidirectional feature of TAM.

Contrary to Applicant's assertions, as stated in the prior Office Action, the specification teaches that TAM can activate transcription in either or both direction when a second DNA component called TIM is placed in either or both directions (see e.g. page 6, lines 9-4). Therefore, the actual occurrence of TIM on either side of TAM generates a bidirectional promoter. Given that Tam and Tim in strategic positions is found in the art, applicants appear to be reciting a new function for an old product. The promoters inherently are bidirectional as they meet the requirements of the bidirectional promoter as described by the instant specification.

Claims 1-10 remain rejected under 35 U.S.C. 102(e) as being anticipated by Tuli et al (US 6,639,065 B1; see entire document) as evidenced by pUC19; see entire document).

Applicant's arguments filed 1-19-2006 have been fully considered, but are not persuasive. Applicants traverse the instant rejection on the grounds that as the examiner notes Tuli has a common inventor with the instant application and that the rejection under 35 USC 102(e) might be overcome by a showing under 37 CFR 1.131 or 1.132. The appropriate showing will be made. Applicant's response is incomplete and do not address the merits of the instant rejection since no showing under either 37 CFR 1.131 or 1.132 has been made of record.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

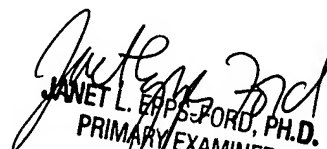
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B. Marvich, PhD whose telephone number is (571)-272-0774. The examiner can normally be reached on M-F (6:30-3:00).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD can be reached on (571)-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maria B. Marvich PhD  
Examiner  
Art Unit 1633  
July 8, 2005

  
JANET L. EPPS-FORD, PH.D.  
PRIMARY EXAMINER